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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,843	01/11/2002	Paul Reiss	1759.2570-CIP 6(2)	7920

7590 04/11/2003

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EXAMINER

MELSON, CANDICE C

ART UNIT	PAPER NUMBER
3732	5

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)
	10/044,843	REISS ET AL. <i>[Signature]</i>
	Examiner Candice C. Nelson	Art Unit 3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-37 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Specifically the application filed 01/11/2002 appears to claim priority to the wrong application, therefore priority has not been granted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiley et al (USPN 6,248,110). Reiley et al disclose “systems and methods to treat fractured or diseased bone by deploying more than a single therapeutic into the bone”. “The systems and methods deploy multiple expandable bodies, which occupy the bone interior volume simultaneously. Expansion of the bodies form cavity or cavities in cancellous bone in the interior bone volume”.

With respect to Claims 2-9, “if desired, the material for the wall 58 can be selected to exhibit generally elastic properties, like latex. Alternatively, the material can be selected to exhibit less elastic properties like silicone. Using expandable bodies 56 with generally elastic or generally semi-elastic properties, the physician monitors the expansion to assure that over expansion and wall failure do not occur. Furthermore, expandable bodies 56 with generally elastic or generally semi-elastic properties will require some form of external or internal restraints to assure proper deployment in bone” (column 10, lines 56-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-37 are rejected under 35 U.S.C. 103(a) as being obvious over Reiley et al (US 2001/0049531 A1) in view of Reiley et al (US 2002/0183778 A1). In the ‘531 document Reiley et al disclose a method for treating bone comprising the steps of inserting a device as defined in Claim 1 inside bone but they do not disclose the method causing directed expansion of the body in cancellous bone and compacting cancellous bone by directed expansion. In the ‘778 document Reiley et al disclose “FIG. 8 shows a deflated balloon 10 being inserted through a cannula 26 into bone” (paragraph 0092). “The balloon is oriented preferably in the bone such that it allows minimum pressure to be exerted on the bone marrow and/or cancellous bone if there is no fracture or collapse of the bone. Such pressure will compress the bone marrow and/or

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cancellous bone against the inner wall of the cortical bone, thereby compacting the bone marrow of the bone to be treated" (paragraph 0093). With respect to Claims 11 and 29, "the primary goal of percutaneous vertebral body augmentation of the present invention is to provide a balloon which can create a cavity inside the vertebral body whose configuration is optimal for supporting bone. Another important goal is to move the top of the vertebral body back into place to retain height where possible, however, both of these objectives must be achieved without fracturing the cortical wall of the vertebral body" (paragraph 0039). As to Claims 12 and 30, "the tibial fracture is shown in FIG. 19A in which a balloon 180 is placed in one side 182 of a tibia 183. The balloon, when inflated, compacts the cancellous bone in the layer 184 surrounding the balloon 180" (paragraph 0130). Furthermore with respect to Claims 13 and 31, "in the case of the proximal humerus 169, a balloon 166 shown in FIG. 18 is spherical and has a base design. It compacts the cancellous bone 168 in a proximal humerus 169" (paragraph 0122). Regarding Claims 14 and 32, "in the case of the femoral head, a balloon 200 is shown as having been inserted inside the cortical bone 202 of the femoral head. The cortical bone surrounds the cancellous bone and this bone is compacted by the inflation of balloon 200" (paragraph 0137). As to Claims 15, 33 and 34 the '778 document discloses compression of the bone marrow and/or cancellous bone against the inner wall of the cortical bone compacts "the bone marrow of the bone to be treated and to further enlarge the cavity in which the bone marrow is to be replaced by a biocompatible, flowable bone material" (paragraph 0093). With respect to Claims 16-19 and 35-37, "a flowable biocompatible filling material, such as methylmethacrylate cement or a synthetic bone substitute, is then directed into the cavity or passage and allowed to set to a hardened condition to provide structural support for the bone" (paragraph 0007). Lastly with

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respect to Claims 21-27, “still another embodiment of the invention is shown in FIG. 3 which is similar to FIG. 1 except that it is round and not a doughnut and includes an inflatable device 109 having three balloon units 110, 112, and 114 which are inflatable and which have string-like restraints 117 which limit the expansion of the balloon units in a direction transverse to the longitudinal axes of the balloon units” (paragraph 0100). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the methods as disclosed by Reiley et al in the ‘778 document to the device as disclosed by Reiley et al in the ‘531 document in order to provide a system and method which is better overall in the fixation of bone.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or

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subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

ccm *COR*
April 7, 2003

Cary E. O'Connor
Cary E. O'Connor
Primary Examiner